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#13.
3/19/03
1638
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Pal Maliga et al.

Serial No. 09/762,105

Filed: April 23, 2001

For: "Translation Control
Elements for High-Level
Protein Expression in the
Plastids of Higher Plants
and Methods of Use Thereof")

) Examiner: Anne R. Kubelik

) Art Unit: 1638

) Response to Paper No: 10

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TRAVERSAL OF RESTRICTION REQUIREMENT

A new restriction requirement under 35 U.S.C. §§121 and 372 was set forth in the Official Action dated December 17, 2002 in the above-identified patent application. The Examiner has withdrawn the restriction requirement set forth in the June 5, 2002 Official Action in favor of the restriction requirement set forth below. It is the Examiner's position that claims 1-28 in the present application are now drawn to five (5), rather than two (2), patentably distinct inventions which are as follows:

Group I: Claims 1-14 drawn to a DNA construct comprising a 5' regulatory region, a leader sequence, and a downstream box element for expressing a heterologous protein in plastids;

Group II: Claims 15-17, all in part, drawn to a plastid transformation vector;

Group III: Claims 15-17, all in part, and 24-26, drawn to a method for transforming rice plastids and plants so produced;

Group IV: Claims 18-23 drawn to a method for transforming monocot plastids;

Group V: Claims 27-28 drawn to a method for modifying codon usage in structural genes.

Further, if Group I is elected, a single nucleotide sequence for Group I must be selected. Additionally, if either Group II or Group III is elected, a single plasmid for the elected Group must be selected. The Examiner also notes that if Group I is elected, then plasmids of Group II and Group III may also be elected if the plasmids contain the element elected from Group I and all of the elements of the DNA constructs described in claim 1.

Applicants respectfully submit that the restriction requirement set forth above is improper for failure to comply with the relevant provisions of the Manual of Patent Examining Procedure (M.P.E.P.) pertaining to unity of invention determinations.

The present application was filed under 35 U.S.C. §371 as a U.S. national stage application under the Patent Cooperation Treaty.

As stated in §1893.03(d) of the M.P.E.P.:

Examiners are reminded that unity of invention (**not restriction**) practice is applicable in international applications (both Chapter I and II) and in national stage (filed under 35 U.S.C. 371) applications...

The principles of unity of invention are used to determine the types of claimed subject matter and the combinations of claims to different categories of invention that are permitted to be included in a single international or national stage patent application. The basic principle is that an application should relate to only one invention or, if there is more than one invention, that applicant would have a right to include in a single application only those inventions which are so linked as to form a single

general inventive concept.

A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art.... Note also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions as amended 01 July 1992 contained in Appendix AI of the M.P.E.P. (Emphasis added.)

It is noteworthy that, during the international stage of this application, claims 1-28 were determined to be drawn to only two (2) patentably distinct inventions by the Examiner in the Written Opinion issued August 30, 2000. The two patentably distinct inventions are:

Group I: Claims 1-26 drawn to a DNA construct comprising a promoter element, a leader, and a downstream box element and a method for the use of the DNA construct for enhanced plastid expression of a heterologous gene;

Group II: Claims 27-28 drawn to a method for modifying codon usage in structural genes.

Plainly, the restriction requirement of December 17, 2002 fails to comply with the established United States Patent and Trademark Office practice of following the international rules regarding unity of invention in the prosecution of applications filed under §371.

Applicants also reiterate the traversal arguments set forth in the communication filed August 9, 2002.

Specifically, Applicants resubmit that the requirement to elect a **single** nucleic acid sequence is inappropriate. Indeed, several pairs of the nucleic acid sequences provided within Group I comprise i) a nucleic acid sequence and ii) a truncated version of that nucleic acid. A complete search of the full-length version of the nucleic acid sequence would inherently provide a complete search for the truncated version. Thus, Applicants submit these pairs of nucleic acids could be searched and examined together without placing any undue burden on the Examiner. An example of such a pair is resubmitted hereinbelow.

Sequence Alignment for SEQ ID NO:14 and 16

Top Line = PrnnLT7g10+DB/Ec (SEQ ID NO:14)

Bottom Line =PrnnLT7g10-DB (SEQ ID NO:16)

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gagctcgctc ccccgccgctc gttcaatgag aatggataag aggctcgtgg gattgacgtg      60
gagctcgctc ccccgccgctc gttcaatgag aatggataag aggctcgtgg gattgacgtg      60

agggggcagg gatggctata tttctgggag ggagaccaca acggtttccc actagaaata      120
agggggcagg gatggctata tttctgggag ggagaccaca acggtttccc actagaaata      120

at tt t g t t t a a c t t t a a g a a g g a g a t a t a c a t a t g g c a a g c a t g a c t g g t g g a c a g g c t a g c      182
a t t t t g t t t a a c t t t a a g a a g g a g a t a t a c a t a t g g c --- ----- -tag c

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This alignment demonstrates that SEQ ID NO: 16 is fully comprised within SEQ ID NO: 14.

A similar argument can be made for other sequences within the claims which are truncations of one another. Other examples of these pairs of sequences include: SEQ ID NOs: 1 and 2, SEQ ID NOs: 3 and 2, SEQ ID NOs: 4 and 5, SEQ ID NOs: 6 and 7, SEQ ID NOs: 9 and 10, SEQ ID NOs: 11 and 12, and SEQ ID NOs: 14 and 16.

Additionally, Applicants respectfully submit to the Examiner that it is clear from the specification that the plasmids of Groups II and III contain the regulatory regions

of Group I. Specific citations for each of the plasmids of Groups II and III are provided below.

Table 1 at page 25 provides a description of the regulatory regions of plasmids pHK30 through pHK43, pHK60 and pHK64. The plasmid names are provided in the far right column and the corresponding regulatory region can be determined from the first and third columns. Specifically, the nomenclature for all of the regulatory regions begins with the rRNA operon σ^{70} -type promoter (Prnn) followed by the leader (L) (first column, Table 1) and then the type of downstream box (DB; third column, Table 1). As an example, the plasmid pHK30 would be determined from Table 1 to have a regulatory region consisting of (Prnn), (LatpB), and (+DBwt) or PrnnLatpB+DBwt as listed in Group I.

Plasmids pMSK53 and pMSK54 contain the regulatory regions PrnnLrbc+DBwt and PrnnLatpB+DBwt, respectively, as described at page 79, lines 5-20. At page 81, lines 1-16, plasmids pMSK35, pMSK45, pMSK48, and pMSK49 are characterized as containing the regulatory region PrnnLT7g10+DB/Ec. Additionally, plasmids pMSK56 and pMSK57 are defined at page 84, line 32 to page 85, line 3 as containing the regulatory regions PrnnLatpB+DBwt and PrnnLrbcL+DBwt, respectively. In summary, the plasmids of Groups II and III contain the regulatory regions of Group I and contain all of the elements of the DNA constructs of claim 1. Therefore, as noted by the Examiner, Groups I, II, and III should at least be rejoined with regard to an elected regulatory region and plasmids containing the regulatory region.

In light of all the foregoing, Applicants respectfully request the restriction requirement be withdrawn or at the very least modified.

In order to be fully responsive to the restriction requirement identified hereinabove, Applicants hereby elect, with traverse, the subject matter of Group I for consideration in this application, namely claims 1-14. These claims are

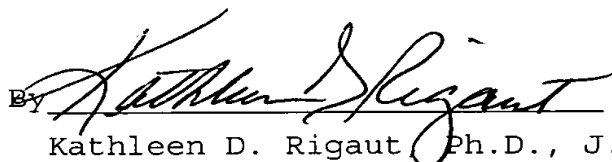
drawn to a DNA construct comprising a 5' regulatory region, a leader sequence, and a downstream box element for expressing a heterologous protein in plastids. Additionally, the Examiner indicated in a telephonic conversation which took place on or about January 22, 2003 that more than one nucleic acid would be searched if the elected nucleic acids fully comprised the sequence of a shorter regulatory element. Thus, Applicants elect SEQ ID NOs: 14 and 16 to comply with the Examiner's requirement to elect specific nucleotide sequences.

Furthermore, Applicants elect, as directed at page four of the Official Action dated December 17, 2002, the plasmids containing SEQ ID NOs: 14 and 16 of Groups II and III. Groups II and III correspond to claims 15-17 drawn to a plastid transformation vector and claims 15-17 and 24-26 drawn to a method for transforming rice plastids and plants so produced, respectively. The plasmids of Groups II and III containing SEQ ID NOs: 14 and 16 are pHK38, pHK40, pMSK35, pMSK45, pMSK48, and pMSK49.

Applicants hereby reserves the right to file one or more continuation applications under 35 U.S.C. §120 on the subject matter of all claims ultimately withheld from consideration in the present application.

Early and favorable action on this application is earnestly solicited.

Respectfully submitted,
DANN, DORFMAN, HERRELL AND SKILLMAN

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